

**The Outcomes of Home-Based Intervention to the Diabetics According to the Health
Belief Model: A Randomized Controlled Trial**

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BACKGROUND

The prevalence of diabetes is steadily increasing around the world and patients are suffering the complications dramatically (International Diabetes Federation [IDF], 2015; TURDEP-II Study Group, Diabetes epidemic in Turkey, 2011). However, for patients with diabetes in the self-management education, the emphasis has been on conducting interventions by determining the beliefs of people with diabetes rather than eliminating the lack of knowledge on the issue (Harvey and Lawson 2009).

Several qualitative studies on the issue have demonstrated that patients with diabetes are unable to establish a balance between their quality of life and medical outcomes associated with the disease, and thus they want to get timely support from medical experts and to understand their responsibility of self-management in line with their beliefs and perceptions (Açıl and Bahar 2017; Frost et al. 2014; Gazmararian et al. 2008). Therefore, it is assumed that nursing interventions based on theory (e.g. Health Belief Model [HBM] etc.) not only would benefit individuals but may also contribute to the production of new knowledge related to disease perception and behavior change (Champion and Skinner, 2008; Dalton, 2012). In studies conducted with patients with diabetes according to the HBM, the results of metabolic control and self-care efficacy have been proved to improve (Kartal ve Özsoy 2006; Olgun ve Altun 2012; Adejoh 2014; Mcelfish et al. 2016; Karimy et al. 2016; Wang et al. 2017). It has been determined that the benefit and severity of their illnesses perceived by patients with diabetes are significantly related to the management of diabetes, and that the perceived barrier, benefit, severity, and self-efficacy account for 20%-60% of health behaviors related to diabetes management (Adejoh 2014; Karimy et al. 2016; Wang et al. 2017).

Among the components of diabetes self-management are compliance with medication, medical nutrition therapy (MNT), physical activity, avoidance of smoking, and adequate and quality sleep (Handelsman et al. 2011). In addition, regular glucose, blood pressure, and lipid regulation controls have been shown to reduce acute and chronic complications of diabetes (Loveman, Rolye, Waugh 2009; Malanda et al. 2012; Alvarado et al. 2017). However, according to the US National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), glucose, blood pressure, and lipid levels are at the recommended level only in 12% of individuals with diabetes. Applications aiming to develop diabetes self-management skills that start in the hospital with the diagnosis of diabetes should be turned into community-based disease management programs performed at home.

In the literature, there are studies indicating that in patients with diabetes, home-care interventions are supported with the use of technology, and ensuring the provision of the

continuity of care (Loandman, Rolye, Waugh 2009; Stone et al. 2010; Rosa et al. 2014). In the Diabetes Prevention and Control Program launched in 2011 in Turkey, the promotion of quality of life was stated as one of the components of the program, and the necessity of maintaining home care services was emphasized (Turkey Ministry of Health Primary Health Services Directorate, 2011). The nurse should be able to define control problems experienced by a patient with diabetes and to plan appropriate nursing interventions (Sousa et al. 2005).

Diabetes is also directly and indirectly associated with health expenditures due to its morbidity and mortality burden (Republic of

Turkey Ministry of Health Primary Health Services Directorate, 2011). It is known that 12% of the world's healthcare expenditures (673 billion US dollars) are spent on diabetes and its complications. In Turkey, the average per capita expenditure on diabetes is 846 US dollars ([IDF], 2015). According to the data released by the Social Security Institution, about 23% of the budget allocated for health in Turkey is spent on diabetes and its complications (<https://www.tubitak.gov.tr/sites/default/files/1003-sab-ttip-2017-1.pdf> 27.03.2017). Of the different public health interventions in Turkey, the one with the highest cost is the monitoring of diabetes (Republic of Turkey, Ministry of Health, Refik Saydam Hygiene Center Presidency, 2004). It has been emphasized that nurses specialized in primary health care can provide high quality care to individuals, improve their health-related outcomes and contribute to reduction in health expenditures (Bahia et al. 2011).

According to the results of a qualitative study conducted within the Health Belief Model, there is a gap in the literature related to studies investigating individual-specific nursing interventions provided with home visits, and assessing the cost of the interventions. Therefore, it is thought that home care provided for individuals with diabetes in line with their perception of their illness will create a difference, and that nurses working in primary healthcare can develop strategies to monitor patients with diabetes.

The aim of the present study is to determine the effects of home-based nursing interventions carried out according to the Health Belief Model on healthcare outcomes of patients with diabetes.

STUDY PROTOCOL

Type of the study

The study was conducted as an intervention (randomized controlled, single blind) one.

Location and Time of the Study

The study was carried out between January 2015 and March 2017 in three districts of İzmir, a province in the western part of Turkey.

The study population and sample

While the patients with diabetes living in districts comprised the study population, the sample was selected from patients with type II diabetes registered to Family Health Centers.

According to the Consolidated Standards of Reporting Trials (CONSORT) recommended for randomized controlled studies, a randomization flow chart was established (Figure 1), and 2460 people with diabetes were assessed for compliance with diabetes (Schulz et al. 2010; Sunay et al. 2013). From the 1081 people with diabetes who met the inclusion criteria, the intervention and control groups each to include 65 individuals were constructed using the "Research Randomizer" computer program. The study was completed with 81 people with diabetes (42 in the intervention group and 39 in the control group). Post hoc power analysis was performed using the G-Power Data Analysis program and the power of the study was determined as 100% at the 95% confidence interval and $p = .05$ significance level.

The participants were not told to which group they were assigned. Thus, the study was conducted as a single-blind study.

Inclusion Criteria:

Volunteering to participate in the study

Having Type 2 diabetes

Not having diabetes-related complications

Having a mobile phone to contact any time

Data Collection Tools

Data Collection Form for patients with Diabetes

This form includes questions about the sociodemographic and disease-related characteristics of patients with diabetes.

Metabolic Control Data Form

The form developed by the researcher in line with the literature was used to compare patients' diabetic control metabolic evaluations and to compare pre- and post-intervention values in the study process (fasting plasma glucose level, postprandial level, HbA1c, BMI, blood pressure, frequency of complication-related hospital admissions). The cost was calculated by comparing the intervention and control groups in terms of the frequency of their hospital admissions. To calculate the cost of hospitalization for each patient, consumables (blood glucose measuring equipment, wound care products, wound cover, sterile gloves, catheter, urine bag, pen needle, infusion pump set) and time spent by the nurse (30 minutes for each patient) were determined. The prices of the consumables were based on the Health Practice Communiqué published on March 25, 2017 (<http://www.resmigazete.gov.tr/main.aspx?home=http://www.resmigazete.gov.tr/eskiler/2017/03/20170325.htm&main=http://www.resmigazete.gov.tr/eskiler/2017/03/20170325.htm> ET. 22.04.2017). The cost of the time spent by the nurse was based on a new graduate nurse's salary and was calculated by using the formula " salary / working time of May 2017 x 0.5 hours".

Health Belief Model Scale in Patients with Diabetes

The scale was developed in China, the validity and reliability study of the Turkish version of the scale was conducted by Kartal and Özsoy (2007). The Cronbach's alpha value was 0.72 and 0.90 respectively (Tan, 2004; Kartal and Özsoy 2007). The subscales of the scale were as follows: perceived susceptibility, perceived severity, perceived benefits, perceived barriers and recommended health behaviors. In the present study, the Cronbach's alpha value was 0.72.

Diabetes Management Self-Efficacy Scale for Patients with Type 2 Diabetes

The scale was developed in 1999, the validity and reliability study of the Turkish version of the scale was conducted by Usta (2001). The Cronbach's alpha value was 0.89 for both versions (Van Der Bijl et al. 1999; Usta 2001). The scale has 4 subscales: nutrition specific and weight, physical exercise, and blood sugar, nutrition general and medical treatment (Kartal and Özsoy 2007; Van Der Bijl et al. 1999). In the present study, the Cronbach's alpha value was 0.93.

Training Booklet and Implementation Steps

A booklet including information on nursing interventions for diabetes was prepared. The training booklet was based on the current literature and the results of the qualitative study conducted on the issue in first step of the PhD thesis. The booklet was revised in line with the opinions obtained from 5 professors who were experts in the field. The International Standard Book Number (978-975-441-462-2 ISBN) for the booklet was obtained by the Presidency of Dokuz Eylül University and published in the Dokuz Eylül University Press.

During the first home visit, the participants in the intervention group were applied the data collection tools, and then nursing interventions in accordance with the subscales of the Health Belief Model by taking into account the individual differences of the participants. The nursing interventions were performed within the scope of the basic dimensions of diabetes management such as nutrition, exercise, medication management, oral care and foot care. In addition, the importance of annual monitoring of HbA1c, blood lipid, albumin / creatinine levels, fundus examination, blood pressure monitoring, sleep hygiene, avoidance of smoking and alcohol was also explained (TEMD; 2011; http://www.tdhd.org/dhd_kitap/13blm.pdf AD.10.10.2014; <http://diabetes.niddk.nih.gov/dm/pubs/statistics/#Complications> AD.15.01.2014; American Diabetes Association 2014). Home visits were paid 3 times at 3-month intervals. After the home visits started, reminder messages supporting the home visit process were sent at two-week intervals.

The participants in the control group were contacted 3 times at 3-month intervals through telephone calls, and were applied the data collection tools. At the end of the study, the participants in the control group were given health training at the Dokuz Eylül University Faculty of Nursing and the training booklet was distributed to them.

Hypotheses of the Study

Patients with diabetes undergoing home-based nursing interventions in line with the HBM

- H1: have higher mean scores for the Health Belief Model Scale than the control group.
- H2: have higher mean scores for the Self-Efficacy Scale than the control group.
- H3: have lower HbA1c levels than the control group.
- H4: have lower blood glucose levels (BGL) than the control group.
- H5: have lower blood pressure levels than the control group.
- H6: have lower BMI levels than the control group.
- H7: have fewer hospital admissions due to an acute or chronic complication than the control group.
- H8: have a lower complication-related cost rate than the control group.

Analysis of the Data

The study data were analyzed using numbers, percentages, the chi-square test, the test for the Significance of the Difference Between Two Means, the Repeated Measures Multivariate Analysis of Variance, Bonferroni-adjusted t-test in dependent groups and multiple regression analysis in the Statistical Package for Social Sciences (SPSS) (23.0) program (Coşansu, 2015; Akgül 2005; Bahar 2004).